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SUBSTITUTE FORM PTO-1449 (MODIFIED)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  (37 C.F.R. §1.98(b))	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	06132/045004
		Serial No.	10/737,270
		Applicant	William D. Thomas Jr. et al.
		Filing Date	December 16, 2003
		Group	Not Yet Assigned
		IDS Filed	January 23, 2004

## U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
	5,412,077	05/02/95	Siber et al.			
	5,530,103	06/25/96	Gristina et al.			
	5,582,827	12/10/96	Siber et al.			
	5,599,539	02/04/97	Carroll et al.			
	5,601,823	02/11/97	Williams et al.			
	5,762,934	06/09/98	Williams et al.			
	5,773,000	06/30/98	Bostwick et al.			

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	<del>WO 94/13284</del>	<del>06/23/94</del>	<del>PCT</del>			
	<del>WO 96/07430</del>	<del>03/14/96</del>	<del>PCT</del>			
	<del>WO 96/12802</del>	<del>05/02/96</del>	<del>PCT</del>			
	WO 97/02836	01/30/97	PCT			

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

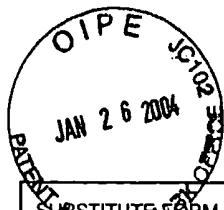
	<del>Alto et al., "Prevention of Clindamycin-Induced Colitis in Hamsters by Clostridium sordelli Antitoxin," Gastroenterology 76:351-355 (1979).</del>
	Gorhior et al., "Protection against Experimental Pseudomembranous Colitis in Gnotobiotic Mice by Use of Monoclonal Antibodies Against Clostridium difficile Toxin A," Infection and Immunity 59:1192-1195 (1991).
	<del>Fekety et al., "Diagnosis and Treatment of Clostridium difficile Colitis," Journal of the American Medical Association 269:71-75 (1993).</del>
	Fernie et al., "Active and Passive Immunization to Protect Against Antibiotic Associated Caecitis in Hamsters," Dev. Biol. Stand. 53:325-332 (1983).

EXAMINER

DATE CONSIDERED

10/8/04

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.



Sheet 2 of 2

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(MODIFIED)U.S. DEPARTMENT OF COMMERCE  
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(37 C.F.R. §1.98(b))

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

	Johnston, "Antibody Responses to Clostridial Infection in Humans," <i>Clinical Infectious Diseases</i> 25:2 S173-177 (1997).
	Johnson et al., "Systemic and Mucosal Antibody Responses to Toxin A in Patients Infected with Clostridium Difficile," <i>Journal of Infectious Diseases</i> 166:1287-1294 (1992).
	<del>Kelly et al., "Anti-Clostridium difficile Bovine Immunoglobulin Concentrate Inhibits Cytotoxicity and Enterotoxicity of C. difficile Toxins," <i>Antimicrobial Agents and Chemotherapy</i> 40:373-379 (1996).</del>
	<del>Kim et al., "Immunization of Adult Hamsters against Clostridium difficile-Associated Ileocolitis and Transfer of Protection to Infant Hamsters," <i>Infection and Immunity</i> 55:2984-2992 (1987).</del>
	<del>Kyne et al., "Prospects for a vaccine for Clostridium difficile," <i>BioDrugs</i> 10:173-181 (1998).</del>
	<del>Leung et al., "Treatment with Intravenously Administered Gamma Globulin of Chronic Relapsing Colitis Induced by Clostridium difficile Toxin," <i>The Journal of Pediatrics</i> 118:633-637 (1991).</del>
	<del>Libby et al., "Effects of the Two Toxins of Clostridium difficile and Immunological Comparison of the Toxins by Cross-Neutralization Studies," <i>Infection and Immunity</i> 36:822-829 (1982).</del>
	<del>Libby et al., "Production of Antitoxins of Two Toxins of Clostridium difficile and immunological Comparison of the Toxins by Cross-Neutralization Studies," <i>Infection and Immunity</i> 35:374-376 (1982).</del>
	<del>Lyerly et al., "Passive Immunization of Hamsters Against Disease Caused by Clostridium Difficile by use of Bovine Immunoglobulin G Concentrate," <i>Infection and Immunity</i> 59:2216-2218 (1991).</del>
	Lyerly et al., "Vaccination Against Lethal Clostridium Difficile Enterocolitis with a Nontoxic Recombinant Peptide of Toxin A," <i>Current Microbiology</i> 21:29-32 (1990).
	<del>Mitty et al., "Clostridium difficile Diarrhea: Pathogenesis, Epidemiology, and Treatment," <i>The Gastroenterologist</i> 2:61-69 (1994).</del>
	Mulligan et al., "Elevated Levels of Serum Immunoglobulins in Asymptomatic Carriers of Clostridium Difficile," <i>Clinic of Infectious Diseases Suppl</i> 4:S239-244 (1993).
	Salcedo et al., "Intravenous Immunoglobulin Therapy for Severe Clostridium difficile Colitis," <i>Gut</i> 41:366-370 (1997).
	<del>Torres et al., "Clostridium difficile Vaccine: Influence of Different Adjuvants and Routes of Immunization on Protective Immunity in Hamsters," <i>Vaccine Research</i> 5:149-162 (1996).</del>
	<del>Torres et al., "Evaluation of Formalin-Inactivated Clostridium difficile Vaccines Administered by Parenteral and Mucosal Routes of Immunization in Hamsters," <i>Infection and Immunity</i> 63:4619-4627 (1995).</del>
	<del>Wemy et al., "Gamma Globulin Administration in Relapsing Clostridium difficile-Induced Pseudomembranous Colitis with Defective Antibody Response to Toxin A," <i>Acta Clinica Belgica</i> 50:36-39 (1995).</del>

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